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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re LIDODERM ANTITRUST LITIGATION	Master File No. 14-md-02521-WHO MDL No. 2521
THIS DOCUMENT RELATES TO: ALL ACTIONS	**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE IN PART EXPERT TESTIMONY OF MR. HARSHA MURTHY (ECF NO. 773)** **ORAL ARGUMENT REQUESTED** Date: September 15, 2017 Time: 2:00 p.m. Courtroom: 2, 17th Floor The Honorable William H. Orrick

I. INTRODUCTION

Mr. Murthy relies on nothing other than experience when opining on the likelihood of a reasonable generic pharmaceutical company launching at-risk. But, experience alone, divorced from any factual analysis, is not sufficient to meet *Daubert* reliability standards. Experience can be the basis to qualify as an expert only if the expert uses that experience to examine "sufficient facts or data" and apply that information "to the facts of the case." Fed. R. Evid. 702. "Expert testimony is useful as a guide to interpreting . . . facts, but it is not a substitute for them." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993).

Just because Mr. Murthy cannot rely on Watson's undisclosed subjective beliefs about its willingness to launch at-risk does not mean that Mr. Murthy is free to ignore all the actual, produced information in this case or industry data to ground his opinion. Mr. Murthy claims that, in his experience, a reasonable generic pharmaceutical company would weigh three factors[1] when deciding whether to launch at-risk: (1) the likelihood of adverse decisions on regulatory approval; (2) the likelihood of an adverse patent trial outcome; and (3) the likelihood that a company would have launch quantities at the time of a potential launch. Mr. Murthy claims that a weighing of those factors would make it "*very unlikely* that a [reasonable] company . . . would have launched a generic version of Endo's Lidoderm patch 'at-risk.'" Murthy Rpt. ¶ 13(a) (Steiner Decl. Ex. 1).[2]

But, Mr. Murthy does not apply any facts or data to weigh these factors. Mr. Murthy merely identifies these factors and then, based solely on his say-so, concludes that no reasonable company would launch at-risk. He does no weighing; he does no analysis; he does not explain what any company he was associated with did in any similar circumstance. He reaches his conclusion by some unknown process. That is exactly the "junk science" that *Daubert* forbids.

[1] As Defendants acknowledge, Mr. Murthy identified a fourth factor—the likelihood and timing of entry of additional generic entrants—but did not address it. Defs.' Opp'n to Mot. to Exclude in Part Expert Testimony of H. Murthy ("Opp'n") at 4, ECF No. 809; Pls.' Mot. to Exclude in Part Expert Testimony of H. Murthy ("Mot.") at 4, ECF No. 773.

[2] Mr. Murthy's report is attached to Steiner Decl. as Ex. 1, ECF No. 773-2. Mr. Murthy's original report has been modified to remove opinions about a "company in Watson's position" and replace them with a "reasonable company."

II. DISCUSSION

Mr. Murthy's report purports to apply case-specific facts to the factors he identified that generic drug companies consider when assessing an at-risk launch. However, as explained in our opening brief and below, Mr. Murthy cites nothing but his own say-so when assessing how a reasonable company would weigh the factors he identified. Because Mr. Murthy has not properly applied any facts to his selected criteria, his opinion on at-risk launch is purely subjective, cannot be examined for reliability and must be excluded.

A. Mr. Murthy Did Not Apply Any Facts Or Data To His Methodology

Mr. Murthy's "methodology" is his selection of criteria he believes, based on his experience, a reasonable generic pharmaceutical company would assess in deciding whether to launch at risk. Defendants acknowledge that Mr. Murthy's opinion using that methodology is based solely on experience. Opp'n at 8 ("An expert may instead base his opinion solely on his experience . . . [Mr. Murthy relies on his] own experiential assessment of how a reasonable [company] would evaluate the pertinent factors . . .."). But, neither *Daubert* nor Rule 702 "requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *United States v. Williams*, 2017 WL 3498694, at *7 (N.D. Cal. Aug. 15, 2017) (*Williams II*") ("'A court making a determination of reliability under *Daubert* and Rule 702 is justified in rejecting the "ipse dixit" of an expert.'") (quoting *United States v. McCluskey*, 954 F. Supp. 2d 1224, 1286 (D.N.M. 2013)).

Mr. Murthy's report provides no analysis of evidentiary facts using the criteria he claims would inform a reasonable company's at-risk launch decision, but instead invokes a conclusory refrain that the existence of the factors themselves compels his conclusion that an at-risk launch was "very unlikely." But, "[p]roper application of the methods is a necessary component of ensuring the reliability of the opinion testimony." *Williams II*, 2017 WL 3498694, at *12. The court's task "'is to analyze not what the experts say, but what basis they have for saying it.'" *Id.* (quoting *Daubert v. Merrell Dow Pharma., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1316 (9th Cir. 1995)). The consideration of how an expert applied his criteria "is critical to a determination of whether the opinion 'rests on a reliable foundation.'" *Id.* at *12 (quoting *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 597 (1993)).

Because he does not analyze any evidence in applying his three criteria, Mr. Murthy has no basis to say that it is unlikely that a company would have launched at-risk. Here, Mr. Murthy cites a few facts that led to his *selection* of the three "likelihood" factors, but then relies only on his say-so when reaching a conclusion about the outcome at which a reasonable company would arrive. Defendants argue that "empirical data" does not need to be cited as support for an expert opinion. Opp'n at 7-8. Plaintiffs are not arguing that studies or surveys are necessary, but rather that an expert must rely on *something* other than his say-so. "'The question is whether an expert's methodology can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability.'" *Williams II*, 2017 WL 3498694, at *10 (quoting *City of Pomona v. SQM N. Am. Corp. (Pomona I)*, 750 F.3d 1036, 1046 (9th Cir. 2014)). "'Opinion based on unsubstantiated and undocumented information is the antithesis of . . . scientifically reliable expert opinion.'" *Id.* (further quoting *Pomona I*, at 1044).

The Ninth Circuit and other circuits have consistently stated that such "*ipse dixit*" from an even-otherwise-qualified expert is insufficient to satisfy the reliability requirements. *Daubert II*, 43 F.3d at 1319 ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). *See also Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 420 (7th Cir. 2005) ("Reliable inferences depend on more than say-so . . ."); *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999) ("[Q]ualifications alone do not suffice. A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method . . . ."). Mr. Murthy's fact-free judgment call must be struck.

1. Mr. Murthy has no support for his opinion on the likely outcomes of the ANDA or the Citizen Petition

Defendants attempt to rehabilitate Mr. Murthy's actual opinion by claiming it was something much more limited than it is. Mr. Murthy's opinion is not, as Defendants imply, merely that "a reasonable pharmaceutical company would not have made any decision on whether to launch" because it had not yet received ANDA approval or resolved the Citizen Petition. Opp'n at 3. Rather, in his report, Mr. Murthy claims to have assessed the *likelihood* of securing all regulatory approvals and

determined that it was unlikely for a reasonable company to launch at-risk. *See* Murthy Rpt. ¶¶ 13, 23.

In their opposition brief, however, Defendants acknowledge that Mr. Murthy limited his review merely to issues of timing, not likelihood: that the FDA had not tentatively approved the ANDA or resolved the Citizen Petition at the time of the settlement. Opp'n at 3, 9. Mr. Murthy also admitted at his deposition that he did no examination of the likelihood of ANDA approval or Citizen Petition denial: he did not look at documents from this case, he did not research industry statistics, and he did not cite to any personal experience as evidence of the likelihood of regulatory approvals. Mot. at 6 (Mr. Murthy testifying that "All I know is, as of this date in April 2012, they had not gotten an ANDA approval" and "The only thing I know is that, as of the dates I was looking at, the citizen petition, there had not been a decision."). Thus, there is no factual basis for Mr. Murthy's speculative opinion that the *likelihood* (or not) of regulatory approval would make at-risk launch "very unlikely." Murthy Rpt. ¶ 13(a).

Moreover, there is no relationship between the "facts" Mr. Murthy cites (that Watson did not have tentative approval or resolution of the Citizen Petition "at the time of the settlement") and his opinion that an at-risk launch was "very unlikely." If he meant that an at-risk launch occurring in May 2012 ("at the time of the settlement") was unlikely, that is true but irrelevant, since Plaintiffs do not claim that Watson would have launched before it received FDA approval. If Mr. Murthy meant that an at-risk launch was unlikely at some later time because Watson did not have tentative approval, his opinion makes no sense, since an at-risk launch could only occur after FDA approval (and resolution of the Citizen Petition). Either way, his opinion is unsupported by any facts, and should be excluded.

2. Mr. Murthy has no support for his opinion on the likely outcome of the patent trial

Again, what Mr. Murthy purports to have analyzed and what Defendants address do not match. Mr. Murthy opines on "the likelihood of an adverse litigation outcome" as a factor that must be weighed when making an at-risk launch determination. *Id*. ¶ 23. However, the facts Defendants point to that Mr. Murthy relied on do not address the *likelihood* of an adverse litigation outcome—rather, Mr. Murthy merely lays out one of the possible outcomes: that *if* Watson launched at-risk and *if* the patent win was reversed by the appellate court, Watson *may* be liable for treble damages. *See* Opp'n at 3, 9.

Indeed, Mr. Murthy admitted that he did no assessment whatsoever of the likelihood of an adverse outcome occurring—he did not do any independent examination of the patent litigation, did not look at any documents produced in this case on Watson's assessment on the outcome of the patent litigation, did not look at industry-wide at-risk launch statistics, and did not rely on the opinions of the patent experts in this case. Mot. at 7-8. Thus, there is no analysis of the factor Mr. Murthy proposes.

All we have is Mr. Murthy's say-so that any unresolved patent litigation—regardless of the merit (or lack of merit) of the claims—would preclude a launch at-risk. But, Mr. Murthy admits that there is no universal view on launching at-risk: "Not all generic companies look at their launches the same way. It is very much a function of the strategy, the decision-making process, the individuals, what is their place in the market. Just as there are different people with different outlooks on life, there are different companies. Generic companies have different views how they look at at-risk launches." ECF No. 773-3 (Steiner Decl. Ex. 2) at 242:8-22 (Murthy Tr.).

Given the acknowledged possible range of outcomes and the different risk tolerances among companies, Mr. Murthy must explain why a reasonable generic company would come to the same conclusion he did, by relying on something other than his say-so. "'Personal opinion, not science, is testifying here.'" *Daubert II*, 43 F.3d at 1319 (quoting *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992)).

3. Mr. Murthy has no basis to opine on the ability of a generic manufacturer to produce generic Lidoderm before September 15, 2013 (the settlement-agreed launch date)

Last, Mr. Murthy purports to assess a "company's manufacturing capabilities and ability to meet demand for the generic product." Murthy Rpt. ¶ 23. Defendants confess that Mr. Murthy relied only on the fact that Watson did not have launch quantities of generic Lidoderm ready to sell *at the time of the settlement*. Opp'n at 4, 9. Mr. Murthy does not examine the *likelihood* of Watson (or a reasonable generic company) having launch quantities when the launch would be considered "at-risk"— i.e., the time between regulatory approval (which occurred in August 2012) and any final appellate decision (which Defendants argue would have been no earlier than October 2013). Mr. Murthy does not explain why not having launch quantities at the time of settlement in May 2012,

months before ANDA approval was expected, leads to the conclusion that Watson had an "inability to supply the entire generic market" and therefore would "weigh heavily against a decision to launch generic Lidoderm 'at risk.'" Murthy Rpt. ¶ 57. We are left with only Mr. Murthy's subjective say-so, speculation that flunks the *Daubert* test.

B. The Cases Defendants Cite Cannot Save Mr. Murthy's Opinion

Defendants cite a handful of cases where an expert could testify based on experience, but they miss the point. In each case cited by Defendants, the testimony was limited to selection of the methodology employed in that industry (like Mr. Murthy's three factors), not to the outcome of the expert's application of the methodology. In *Icon-IP Pty Ltd. v. Specialized Bicycle Components, Inc.*, 87 F. Supp. 928, 946 (N.D. Cal. 2015), a patent case, a biking magazine journalist was qualified to review bike saddles and opine on characteristics that consumers favor. In *Lovett v. Omni Hotels Management Corp.*, No. 14-cv-02844-RS, 2016 WL 777781, at *4-5 (N.D. Cal. Feb. 29, 2016), a hotel executive was qualified to testify about standard industry practices related to risk assessment. In *Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Management, Inc.*, 618 F.3d 1025, 1043 (9th Cir. 2010), a marketing executive was qualified to testify about the standard practice of conducting a trademark search before offering a new product. In *Hangarter v. Provident Accident and Life Insurance Co.*, 373 F.3d 998, 1015-16 (9th Cir. 2004), an insurance executive was qualified to testify about an insurance company's standard practice in workers' compensation coverage determinations. In each case, the opinion was limited to what a company *would consider* when assessing the issue raised in the case, but did not reach a conclusion about the outcome of those considerations. That is unlike the situation here, where Mr. Murthy offers both a methodology of his own devising (his three factors) and then, with not a single evidentiary citation, offers his subjective, personal opinion that a reasonable company would not launch at-risk, as a purported application of his methodology.

III. CONCLUSION

Without addressing any facts about the likelihood of obtaining ANDA approval, prevailing in the patent litigation, and amassing launch quantities, Mr. Murthy has nothing to underpin his opinion that a reasonable company would not launch at-risk. His opinion on the likelihood of a reasonable company launching at-risk therefore must be excluded.

Dated: August 25, 2017

Respectfully submitted,

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ATTESTATION

I, Renae D. Steiner, am the ECF User whose identification and password are being used to file this Plaintiffs' Reply in Support of Their Motion to Exclude in Part Expert Testimony of Mr. Harsha Murthy. I attest under penalty of perjury that concurrence in this filing has been obtained from all counsel.

DATED: August 25, 2017 /s/ *Renae D. Steiner*

CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2017, I electronically filed the foregoing document using the CM/ECF system, which will send notification of such filing to all counsel of record registered in the CM/ECF system. I also caused a copy of the foregoing document to be served via email on counsel of record for all parties.

/s/ *Renae D. Steiner*